DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 5, 2014

Resonance Innovations LLC
% Mr. Randall Jones
President & CEO
9840 South 140th Street, Suite 8
OMAHA NE 68138

Re: K142676
Trade/Device Name: Siemens 3.0T PROCURE Array Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: November 7, 2014
Received: November 12, 2014

Dear Mr. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K142676

Device Name

Siemens 3.0T PROCURE Array Coil

Indications for Use *(Describe)*

The coil is indicated for use by the order of a physician to be used as an accessory to a Siemens 3.0T magnetic resonance scanner for general human anatomy imaging as supported by the scanner. These images, when interpreted by a trained physician, may assist in medical diagnosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Resonance Innovations, LLC
9840 S. 140th St., Suite 8
Omaha, NE 68138
(O) 402.934.2650 (F) 402.778.9699
www.scanmed.com

**Section 8. 510(k) Summary**

| | |
|---|---|
| **Submitter's Name:** | Resonance Innovations LLC |
| **Submitter's Address:** | 9840 South 140th St., Suite 8<br>Omaha, NE 68138 |
| **Submitter's Telephone:** | 402-934-2650 |
| **Submitter's Contact:** | Randall Jones, President |
| **Date 510(k) Summary prepared:** | September 12, 2014 |
| **Proprietary Name:** | Siemens 3.0T PROCURE™ Array Coil<br>Model 588SI3001 |
| **Common or Usual Name:** | MRI coil(s) |
| **Classification Name:** | Coil, Magnetic Resonance, Specialty |
| **Classification Code:** | MOS |
| **Predicate Device:** | 1.5T and 3.0T GE PROCURE™ Array Coil, K140606 |

**Description of the Device**

The Siemens 3.0T PROCURE™ Array Coil interfaces with a 3.0T 16-channel Siemens MRI scanner and provides high-quality images of the reproductive and urological anatomies in an easy-to-position, wearable, and very flexible design. This lightweight SemiFlex™ design facilitates effortless and accurate positioning similar to wearing a diaper and positions the multiple antenna elements as close as possible to the target anatomies regardless of patient size. The enclosure for the antenna set is made of flexible liquid impermeable, biocompatible materials, and the coil is accompanied by disposable liners (USP Class 6 PET) easily changed between patients, should scanning without clothing be desired. The coil design and materials used for manufacture are identical to standard MRI coil technology that has existed for several years. The coil uses similar blocking networks and impedance matching circuits, and it does not transmit energy into the patient, neither predicate nor current submission.

This phased-array coil also accommodates popular biopsy systems, both delivered via an opening near the anus and/or vagina, neither included in the scope of this submission as they are independently operated and cleared by the FDA.

Resonance Innovations, LLC
9840 S. 140th St., Suite 8
Omaha, NE 68138
(O) 402.934.2650 (F) 402.778.9699
www.scanmed.com

| Device Model Number | Device Description |
|---|---|
| 588SI3001 | Siemens 3.0T PROCURE™ Array Coil |

**Intended Use**

The intended use of this Siemens 3.0T PROCURE™ Array Coil is to provide high-quality images of the reproductive and urological anatomies in an easy-to-position, wearable, and very flexible design.

**Indications for Use**

The coil is indicated for use by the order of a physician to be used as an accessory to a Siemens 3.0T magnetic resonance scanner for general human anatomy imaging as supported by the scanner. These images, when interpreted by a trained physician, may assist in medical diagnosis.

**Technological Characteristics**

The comparison between the predicate and the current submission is described, below.

1. **Design**. This submission is for a dedicated coil that may give diagnostic quality images of the reproductive and urological anatomies. It is a multi-channel coil with all channels designed to work at once, receive-only, in conjunction with the system body coil. The predicate multi-channel GE PROCURE™ Array Coil covers the identical anatomy, also working as receive-only to the body coil. Both predicate and modified coils have semi-flexible anterior and posterior sections, with an antenna section between the legs. The modified device has been slightly modified to integrate with the Siemens MRI scanner. All design principles employed are mature and well-known throughout the industry.
2. **Principles of operation**: The scientific principles of operation (magnetic resonance) are identical between the predicate and modified devices. Theory of operation is very well understood throughout the industry.
3. **Materials**. The same materials are used in the construction of the predicate and modified device. All internal circuitry is encapsulated in flame retardant EVA foam, then completely covered with a nylon fabric or compressed EVA. This nylon fabric has been successfully used for over 10 years in the predicate device with no reported biocompatibility issues. Both modified and predicate devices have been tested for mechanical and electrical safety using IEC60601-1 3rd Edition, which for our application is identical to ES60601-1.
4. **Chemical Composition**. Both predicate and modified devices have a successful biocompatibility track record, as demonstrated by cytotoxicity testing and by their history of use in previously cleared devices.

Resonance Innovations, LLC
9840 S. 140th St., Suite 8
Omaha, NE 68138
(O) 402.934.2650 (F) 402.778.9699
www.scanmed.com

5. **Energy Source**. This device is a receive-only coil that does not generate its own power, but rather is controlled by the MRI system as the energy source.

**Non-Clinical Tests**

The predicate and current submission have been subject to similar risk management studies, as listed below, and determined to be substantially equivalent.

1. Blocking network analysis
2. SNR and uniformity analysis
3. Risk management (including hazard analysis and FMEA)
4. Heat testing
5. Compliance testing to IEC60601-1 3rd Edition. IEC60601-1 was chosen for compliance in other world markets. A gap analysis of ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and, a2:2010/(r)2012 with IEC60601-1 was performed and for our devices, the US deviations described by ES60601-1 do not modify the requirements of IEC60601-1. Consequently, we are compliant with ES60601-1.

**Clinical Tests**

Analyses in all 3 planes (sagittal, coronal, and axial) were run on the Siemens 3.0T PROCURE™ Array Coil to show that the anatomies of the submitted and predicate coils have substantial equivalence. Both predicate and modified devices are designed for imaging the reproductive and urological anatomies.

**Substantial Equivalence Decision**

As described in this summary, the modified device is substantially equivalent to the predicate device based on the analysis herein. The modified device raises no new concerns of safety or efficacy.